

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALCON RESEARCH, LTD.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
MYLAN PHARMACEUTICALS INC. and)
MYLAN INC.,)
)
Defendants.)

COMPLAINT

Plaintiff Alcon Research, Ltd. (“Alcon”), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”) of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Alcon’s TRAVATAN Z® (travoprost ophthalmic solution) 0.004% (“TRAVATAN Z”) prior to the expiration of U.S. Patent Nos. 8,268,299 (“the ’299 patent”), 8,323,630 (“the ’630 patent”), and 8,388,941 (“the ’941 patent”).

PARTIES

2. Plaintiff Alcon is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

3. Upon information and belief, defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

4. Upon information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

5. Upon information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc. Except where otherwise noted, Mylan Pharmaceuticals and Mylan Inc. are referred to collectively herein as "Mylan."

JURISDICTION AND VENUE

6. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 1391, and 1400(b).

7. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Inc.

8. Upon information and belief, Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district with the authorization, participation, or assistance of, or in concert with, Mylan Inc.

9. Upon information and belief, Mylan Inc. has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Mylan Inc. has had persistent and continuous

contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district with the authorization, participation, or assistance of, or in concert with, Mylan Pharmaceuticals.

10. Upon information and belief, Mylan Inc. and/or Mylan Pharmaceuticals regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Mylan Inc. and Mylan Pharmaceuticals have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

11. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. Mylan Inc.'s February 28, 2013, Form 10-K (filed with the United States Securities and Exchange Commission) states that Mylan Inc.'s "sales in the United States are derived principally through our wholly owned subsidiary, Mylan Pharmaceuticals Inc. ('MPI'), our primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary." The Form 10-K also reports the income of Mylan Pharmaceuticals Inc. The Mylan Web site, appearing at www.mylan.com, provides information about both Mylan Inc. and Mylan Pharmaceuticals. Mylan Inc. is divided into a number of business units, including the "Generics" business. Upon information and belief, Mylan Pharmaceuticals in whole or in part comprises this "Generics" business, particularly within the United States.

12. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have overlapping officers and directors, with management and operation of Mylan Pharmaceuticals and the Generics business occurring, at least in part, at the respective headquarters of both Mylan

Inc. and Mylan Pharmaceuticals. Upon information and belief, Mylan Inc. issues press releases when generic drugs are approved by FDA or when other events concerning the commercialization of a generic drug occur involving its Generics business.

13. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals conduct business throughout the United States, including Delaware, under the trade name "Mylan Pharmaceuticals."

14. Upon information and belief, Mylan Pharmaceuticals, under its "Mylan Pharmaceuticals" trade name, is registered, under 24 Del. C. § 2540, to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy. Mylan Pharmaceuticals is also registered to do business in Delaware and has appointed a registered agent in Delaware for service of process.

15. Upon information and belief, Mylan Pharmaceuticals' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

16. Upon information and belief, Mylan Inc. and/or Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware.

17. Upon information and belief, litigating patents covering FDA-approved branded drug products is a central feature of Mylan Inc. and Mylan Pharmaceuticals' business model. According to a July 15, 2013, press release, "Mylan has 173 ANDAs pending FDA approval representing \$82.9 billion in annual sales." Upon information and belief, a significant number of these pending ANDAs involve challenges to one or more of an innovator's patents in

which Mylan has certified that “such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals regularly engage in patent litigation concerning FDA-approved branded drug products in this District and consent to jurisdiction in this District, including by filing counterclaims in patent litigation in this District.

BACKGROUND

18. TRAVATAN Z is an ophthalmic solution for topical administration to the eye. The active ingredient in TRAVATAN Z is travoprost. TRAVATAN Z is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

19. The '299 patent, entitled “Self Preserved Aqueous Pharmaceutical Compositions,” was duly and legally issued on September 18, 2012. Alcon Research, Ltd. is the assignee of and owns the '299 patent. A true and correct copy of the '299 patent is attached hereto as Exhibit A and is incorporated herein by reference.

20. The '630 patent, entitled “Self-Preserved Aqueous Pharmaceutical Compositions,” was duly and legally issued on December 4, 2012. Alcon Research, Ltd. is the assignee of and owns the '630 patent. A true and correct copy of the '630 patent is attached hereto as Exhibit B and is incorporated herein by reference.

21. The '941 patent, entitled “Self Preserved Aqueous Pharmaceutical Compositions,” was duly and legally issued on March 5, 2013. Alcon Research, Ltd. is the assignee of and owns the '941 patent. A true and correct copy of the '941 patent is attached hereto as Exhibit C and is incorporated herein by reference.

22. The '299 patent, '630 patent, and '941 patent have each been listed in connection with TRAVATAN Z in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, maintained by the FDA, commonly known as the "Orange Book."

23. By letter dated June 12, 2013 (the "Notice Letter"), Mylan Pharmaceuticals notified Alcon that Mylan Pharmaceuticals had submitted to the FDA an ANDA, No. 20-5050, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution USP, 0.004% ("Mylan's ANDA Product") prior to the expiration of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Mylan's ANDA Product is a drug product that is a generic version of TRAVATAN Z, containing the same or equivalent ingredients in the same or equivalent amounts.

24. The purpose of Mylan's submission of ANDA No. 20-5050 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product prior to the expiration dates of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Mylan is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product prior to the expiration of the '299, '630, and '941 patents.

COUNT I
(Infringement of U.S. Patent No. 8,268,299)

25. Alcon incorporates each of the preceding paragraphs 1–24 as if fully set forth herein.

26. Upon information and belief, Mylan's ANDA Product falls within the scope of one or more claims of the '299 patent.

27. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '299 patent.

28. Upon information and belief, Mylan filed as a part of ANDA No. 20-5050 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '299 patent, asserting that the claims of the '299 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

29. Mylan's submission of ANDA No. 20-5050 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product prior to the expiration of the '299 patent was an act of infringement of the '299 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 20-5050.

31. Upon information and belief, Mylan has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 20-5050.

32. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 20-5050 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

33. The foregoing actions by Mylan constitute and/or will constitute infringement of the '299 patent and active inducement of infringement of the '299 patent.

34. Upon information and belief, Mylan has acted, and will continue to act, with full knowledge of the '299 patent and without a reasonable basis for believing that it would not be liable for infringing the '299 patent and actively inducing infringement of the '299 patent.

35. Alcon will be substantially and irreparably damaged by infringement of the '299 patent. Accordingly, unless Mylan is enjoined from infringing the '299 patent and actively inducing infringement of the '299 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

36. An actual case or controversy exists between Alcon and Mylan with respect to infringement of the '299 patent.

COUNT II
(Infringement of U.S. Patent No. 8,323,630)

37. Alcon incorporates each of the preceding paragraphs 1–36 as if fully set forth herein.

38. Upon information and belief, Mylan's ANDA Product falls within the scope of one or more claims of the '630 patent.

39. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '630 patent.

40. Upon information and belief, Mylan filed as a part of ANDA No. 20-5050 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '630 patent, asserting that the claims of the '630 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

41. Mylan's submission of ANDA No. 20-5050 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product

prior to the expiration of the '630 patent was an act of infringement of the '630 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 20-5050.

43. Upon information and belief, Mylan has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 20-5050.

44. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 20-5050 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

45. The foregoing actions by Mylan constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '630 patent.

46. Upon information and belief, Mylan has acted, and will continue to act, with full knowledge of the '630 patent and without a reasonable basis for believing that it would not be liable for infringing the '630 patent and actively inducing infringement of the '630 patent.

47. Alcon will be substantially and irreparably damaged by infringement of the '630 patent. Accordingly, unless Mylan is enjoined from infringing the '630 patent and actively inducing infringement of the '630 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

48. An actual case or controversy exists between Alcon and Mylan with respect to infringement of the '630 patent.

COUNT III
(Infringement of U.S. Patent No. 8,388,941)

49. Alcon incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. Upon information and belief, Mylan's ANDA Product falls within the scope of one or more claims of the '941 patent. In addition, upon information and belief, the manufacture of Mylan's ANDA Product falls within the scope of one or more claims of the '941 patent.

51. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '941 patent.

52. Upon information and belief, Mylan filed as a part of ANDA No. 20-5050 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '941 patent, asserting that the claims of the '941 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

53. Mylan's submission of ANDA No. 20-5050 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product prior to the expiration of the '941 patent was an act of infringement of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 20-5050.

55. Upon information and belief, Mylan has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage

in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 20-5050.

56. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 20-5050 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

57. The foregoing actions by Mylan constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '941 patent.

58. Upon information and belief, Mylan has acted, and will continue to act, with full knowledge of the '941 patent and without a reasonable basis for believing that it would not be liable for infringing the '941 patent and actively inducing infringement of the '941 patent.

59. Alcon will be substantially and irreparably damaged by infringement of the '941 patent. Accordingly, unless Mylan is enjoined from infringing the '941 patent and actively inducing infringement of the '941 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

60. An actual case or controversy exists between Alcon and Mylan with respect to infringement of the '941 patent.

WHEREFORE, Alcon requests the following relief:

- (a) A judgment that Mylan has infringed the '299 patent and will infringe and actively induce infringement of the '299 patent;
- (b) A judgment that Mylan has infringed the '630 patent and will infringe and actively induce infringement of the '630 patent;
- (c) A judgment that Mylan has infringed the '941 patent and will infringe and actively induce infringement of the '941 patent;

(d) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, be not earlier than the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, or the inducement of any of the foregoing, prior to the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

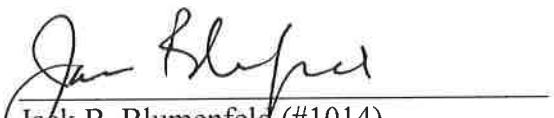
(f) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299 patent, prior to the expiration date of the '299 patent, will infringe and/or actively induce infringement of the '299 patent;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '630 patent, prior to the expiration date of the '630 patent, will infringe and/or actively induce infringement of the '630 patent;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '941 patent, prior to the expiration date of the '941 patent, will infringe and/or actively induce infringement of the '941 patent;

- (i) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (j) An award of Alcon's costs and expenses in this action; and
- (k) Such further and other relief as this Court may deem just and proper.

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